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Evaluation of the Rapid BioStar Optical Immunoassay for Detection of *Chlamydia trachomatis* in Adolescent Women▽

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We evaluated the performance of the BioStar Chlamydia OIA (optical immunoassay) in adolescent females ($n = 261$) from an inner city population. With a reference standard of two different nucleic acid amplification tests, the sensitivity and specificity of the BioStar Chlamydia OIA were 59.4 and 98.4%, respectively. Due to its relatively low sensitivity, the BioStar Chlamydia OIA should only be used in conjunction with more sensitive laboratory tests unless laboratory tests are unavailable or timely return for treatment is unlikely.

Chlamydia trachomatis is the most common sexually transmitted bacterial infection in the world (4). In a majority of people, *C. trachomatis* infection is asymptomatic or causes only mild clinical symptoms. As a result, few infected people seek medical care and treatment, leading to continued transmission to sexual partners (7). In part, this helps explain the relatively high prevalence of *C. trachomatis* infection throughout the world, including countries with advanced medical care and public health programs. Antibiotic treatment is highly effective against *C. trachomatis* infection. Appropriate therapy lowers the risk for development of pelvic inflammatory disease and other sequelae of infection, which include chronic pelvic pain, ectopic pregnancy, and infertility (10). The development of highly sensitive nucleic acid amplification tests (NAATs) has facilitated the screening and detection of *C. trachomatis* infections (1). However, like *C. trachomatis* culture, which was the historical "gold standard" method for the detection of *C. trachomatis* infection, NAATs are only performed in qualified clinical diagnostic laboratories. Patients with a positive NAAT result who are not presumptively treated at the time of their clinic visit are required to return for antibiotic treatment. Among adolescents, who usually have low rates of return, the risk of continued transmission with lack of therapy remains an important concern (11). Even in patients who return for treatment, a long delay between diagnosis and treatment increases the risk for the development of pelvic inflammatory disease, as well as for the transmission of *C. trachomatis* to sex partners. A potential solution to this problem is the use of rapid diagnostic tests that are performed at the point of care, so that patients are tested and treated during the same visit.

The BioStar Chlamydia OIA (optical immunoassay) is a rapid test that was developed for the detection of *C. trachomatis* in women in physician's office- or clinic-based settings, and it does not require specialized equipment. The performance of the BioStar Chlamydia OIA was previously evaluated for the detection of *C. trachomatis* in neonatal conjunctivitis (8) and in urogenital infections of women attending sexually transmitted disease (STD) clinics (6, 12). In this study, we evaluated, for the first time, the performance of the BioStar Chlamydia OIA in an inner city adolescent female population (5). Two hundred sixty-one female adolescent patients, 13 to 19 years old, who were enrolled in a larger longitudinal study at a public pediatric clinic in Atlanta, GA, were included in our sample (5). The study was reviewed and approved by Institutional Review Boards at the Centers for Disease Control and Prevention and Emory University. Sexually active, human immunodeficiency virus-negative, nonpregnant adolescent females aged 13 to 19 years who had not received antibiotics within the previous 30 days and had a clinical indication for a pelvic examination were enrolled with their written consent or, if the adolescents were <18 years old, with their assent and the consent of a parent or guardian. Endocervical swab specimens for the BioStar Chlamydia OIA, culture, enzyme immunoassay, and the NAATs were collected by clinicians during the pelvic examination. The BioStar Chlamydia OIA (BioStar, Inc., Boulder, CO) and all of the other diagnostic tests were performed according to the manufacturer's protocol and specifications (5).

With culture as the reference standard, the sensitivity and specificity of the BioStar Chlamydia OIA in our study were 78.6 and 97.2%, respectively. In a previous study of patients with neonatal conjunctivitis that also used culture as the reference standard, the sensitivity and specificity of the BioStar Chlamydia OIA were 94.2 and 97%, respectively (8). The difference in sensitivity observed in these two studies may be due to differences in the sources of the specimens (ocular versus genital), to differences in the populations (newborns versus adolescents), or to differences in culture methodologies.

With an independent superior reference standard, which was based on concordant positive ligase chain reaction and transcription-mediated amplification assay results (2), the sensitivity and specificity of the BioStar Chlamydia OIA were 59.4 and 98.4%, and those of culture were 76.8 and 97.9%, respectively. In a previously published study evaluating the performance of the BioStar Chlamydia OIA on endocervical specimens from women attending an STD clinic, the authors used a

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multitest reference standard that was based on the results of culture, immunofluorescent-antigen detection assay, and PCR (6). The specificity of the BioStar Chlamydia OIA reported in this STD study was 97%, which is similar to that found in our study, but the sensitivity was higher (73.8%). Two additional published STD studies have investigated the performance of the BioStar Chlamydia OIA. In a study performed in Indonesia, the sensitivity and specificity of the BioStar Chlamydia OIA with ligase chain reaction as the reference standard were 31.6 and 98.9%, respectively (13). No explanation was provided for the poor sensitivity of the BioStar Chlamydia OIA in this study, which differed from that of other reports. In a second study, the performance of the BioStar Chlamydia OIA was compared to that of direct fluorescent-antibody assay, culture, and NAATs (12). The sensitivity and specificity of the BioStar Chlamydia OIA were 64.2 and 99.1%, respectively. In this study, the BioStar Chlamydia OIAs were performed in small batches at a specialized laboratory by an experienced technologist rather than in clinical settings at the point-of-care facility, as in our study.

The quality of the reference standard is critical in establishing the true sensitivity of diagnostic tests (2). It is not surprising, therefore, that the sensitivity of the BioStar Chlamydia OIA in our study was lower than that reported in previous studies, which used the results of less sensitive tests as reference standards. Based on similar considerations, it was predicted that the published sensitivities of the BioStar Chlamydia OIA and other commercially available rapid tests were overestimated because they were evaluated against culture or other, less sensitive, tests (9). Considering the relatively high sensitivity of the NAATs used as a reference standard in our study, it is likely that the performance of the BioStar Chlamydia OIA reported here is more accurate than that previously reported.

In our study, 41 out of the 44 participants who were positive by the BioStar Chlamydia OIA and waited for the OIA results were treated; 3 participants elected not to wait, although they were counseled about the test. Of the 41 participants who were treated based on a BioStar Chlamydia OIA positive result, 14 (34.1%) would have been treated based on clinical signs; however, 27 (65.9%) would have left the clinic without treatment. In a study addressing the potential benefits of rapid tests with regard to numbers of patients treated and cost effectiveness, Gift et al. have calculated that in settings in which the rate of return of the patients for treatment is poor (e.g., less than 65%), a rapid test with a sensitivity as low as 63% would lead to the treatment of more cases than a highly sensitive laboratory test such as PCR (3). Because our study was part of a larger follow-up multiobjective study in which the patients returned to the clinic frequently for other purposes, we were unable to determine the rate of return for treatment in our population, but this rate has been reported to be low for adolescents (11).

In summary, by using an improved reference standard, we have shown that the sensitivity of the BioStar Chlamydia OIA for the detection of *C. trachomatis* in cervical specimens collected from adolescent women was close to 60%. Therefore, due to its relatively low sensitivity, the BioStar Chlamydia OIA should be used in conjunction with more sensitive diagnostic tests whenever these tests are available. In settings where the likelihood of a timely return for treatment is low or where more sensitive diagnostic tests are not available, the BioStar Chlamydia OIA may be useful provided that appropriate counseling is provided regarding the uncertainty of a negative result.

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